

Remarks

Introduction

Claims 1-13 were pending. By way of this response, claims 1, 6, 7, 11, 12, and 13 have been amended, and claim 14 has been added. Support for the amendments to claims can be found in the application as originally filed, and no new matter has been added. For example, support for the amendments to the claims and the new claim can be found in original claims 6 and 12, and at page 23, lines 14-18, and in the examples. Accordingly, claims 1-14 are currently pending.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-5, 7-11, and 13 have been rejected under 35 U.S.C. § 112, first paragraph.

Independent claims 1, 7, and 13 have been amended to include the subject matter of independent claims 6 and 12, which the Examiner indicates as being enabled since claims 6 and 12 have not been rejected under 35 U.S.C. § 112, first paragraph. For example, claims 1, 7, and 13 now each recites that the botulinum toxin is locally administered in therapeutically effective amounts.

In view of the above, applicant submits that the claims satisfy the requirements of 35 U.S.C. § 112, first paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejection Under 35 U.S.C. § 102

Claims 1-4, 6-10, and 12-13 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pohl et al. Claims 1-3, 6-9, and 12 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kennedy et al. Claims 1-12 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Gassner et al. (U.S. Pat. No. 6,447,787).

The present claims have been amended as set forth above, and applicant traverses the rejections as they relate to the present claims.

Pohl et al. discloses treatment of pressure ulcers by serial casting in patients with severe muscle spasticity. Pohl et al. discloses that, in one patient, botulinum toxin was injected to reduce the muscle spasms and muscle tone (table 1 and page 37, left column, first full paragraph).

Kennedy et al. discloses that BOTOX (a botulinum toxin-containing composition) can be injected into spastic muscles to control muscle spasm (page 22, middle column, third paragraph). Kennedy further discloses that pressure sores can develop from muscle cramping (page 22, left column, fourth paragraph).

Gassner et al. discloses that botulinum toxin can be injected into muscles to paralyze the muscles to enhance wound healing (column 1, lines 62-65). Gassner et al. further discloses that botulinum toxin is disclosed used to paralyze muscles to increase the rate of scar healing and provide a better cosmetic result (column 2, lines 56-58).

Applicant submits that the cited references do not disclose, teach, or suggest the present invention. For example, the cited references do not disclose, teach, or even suggest locally administering a botulinum toxin to treat a pressure sore or prevent the development of a pressure sore without substantially paralyzing a muscle, as recited in the present claims.

As discussed above, Pohl et al. does not disclose administration of a botulinum toxin to treat a pressure sore. In contrast, Pohl et al. discloses serial casting to treat pressure ulcers associated with severe spasticity. The only disclosure of Pohl et al. regarding administration of botulinum toxin is to reduce muscle spasticity. Thus, applicant submits that Pohl et al. does not disclose, teach, or even suggest administration of a botulinum toxin to treat or prevent a pressure sore without substantially paralyzing a muscle, as recited in the present claims.

Similarly, Kennedy et al. does not disclose administration of a botulinum toxin to treat a pressure sore. In contrast, Kennedy et al. specifically discloses that botulinum toxin is administered to spastic muscles to control muscle spasm. Thus, applicant submits that Kennedy et al. does not disclose, teach, or even suggest administration of a botulinum toxin to treat or prevent a pressure sore without substantially paralyzing a muscle.

Likewise, Gassner et al. does not disclose administration of a botulinum toxin to treat a pressure sore without

substantially paralyzing a muscle. In contrast, Gassner et al. specifically discloses injecting muscles with botulinum toxin to paralyze the muscles to reduce tension on a surgical wound. Thus, applicant submits that Gassner et al. does not disclose, teach, or even suggest administration of a botulinum toxin to treat or prevent a pressure sore without substantially paralyzing a muscle.

Furthermore, applicant submits that each of the cited references specifically teaches injecting spastic muscles with botulinum toxin to paralyze the muscles. Thus, each of the cited references taken alone or in any combination, actually teaches away from the presently claimed invention, which provides for administration of a botulinum toxin without substantially paralyzing a muscle. Simply put, the references, singly or in any combination, provide no motivation to a person of ordinary skill in the art to practice the presently claimed invention.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In view of the above, applicant submits that the present claims, that is claims 1-14, are not anticipated by Pohl et al., Kennedy et al., or Gassner et al. under 35 U.S.C. § 102, and are unobvious from and patentable over Pohl et al, Kennedy et al.,

and Gassner et al., taken alone or in any combination, under 35 U.S.C. § 103.

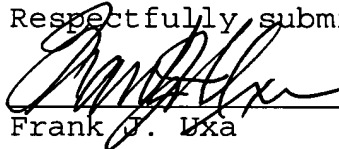
Conclusion

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. § 112, first paragraph, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-14 are allowable. Therefore, applicant requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: \_\_\_\_\_

5/2/05

Respectfully submitted,



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